

WHAT IS CLAIMED IS:

1 An isolated nucleic acid molecule encoding a differentially expressed prostate cancer antigen 3 (PCA3) mRNA containing an additional sequence between exon 3 and exon 4a, thereby giving rise to a long PCA3 mRNA.

2. The isolated nucleic acid molecule of claim 1, wherein said additional sequence interrupts the open reading frame of a PCA3 protein, thereby yielding a truncated PCA3 protein

3 The isolated nucleic acid molecule according to claim 1, comprising a polynucleotide sequence at least 90% identical to a sequence selected from the group consisting of:

(a) a nucleotide sequence as set forth in SEQ ID NO:1,

(b) a nucleotide sequence encoding a differentially expressed PCA3 polypeptide comprising the complete amino acid sequence in SEQ ID NO:3; and

(c) a nucleotide sequence complementary to any of the nucleotide sequences in (a) or (b).

4 The isolated nucleic acid molecule according to claim 1, wherein the molecule comprises the nucleotide sequence encoding PCA3 as set forth in SEQ ID NO:1

5 The isolated nucleic acid molecule according to claim 1, wherein the molecule encodes the polypeptide comprising the complete amino acid sequence set forth in SEQ ID NO:3.

6 An isolated nucleic acid molecule consisting of 10 to 50 nucleotides which specifically hybridizes to a differentially expressed long PCA3 mRNA comprising an additional PCA3 sequence between exon 3 and exon 4a, wherein said nucleic acid molecule is or is complementary to a nucleotide sequence consisting of at least 10 consecutive nucleotides from said PCA3 sequence, as set forth in SEQ ID NO 4

7 A method of detecting differentially expressed PCA3 mRNA in a sample comprising:

- a) contacting said sample with the nucleic acid molecule according to claim 6, under conditions such that hybridization occurs, and
- b) detecting the presence of said molecule bound to PCA3 mRNA.

8 The method of claim 7, wherein a quantitation of a short PCA3 mRNA with respect to said long PCA3 mRNA enables a determination of the malignant status of a prostate.

9. A kit for detecting the presence of differentially expressed PCA3 mRNA in a sample comprising at least one container means having disposed therein the nucleic acid molecule according to claim 6.

10. A recombinant nucleic acid molecule comprising, 5' to 3', a promoter effective to initiate transcription in a host cell and the nucleic acid molecule according to claim 1.

11. A cell that contains the recombinant nucleic acid molecule according to claim 10.

12. A non-human organism that contains the recombinant nucleic acid molecule according to claim 10.

13. A purified differentially expressed PCA3 polypeptide, comprising an additional sequence between exon 3 and exon 4a, which interrupts a PCA3 open reading frame, thereby shortening said PCA3 polypeptide, or an epitope-bearing portion thereof.

14. The purified differentially expressed PCA3 polypeptide of claim 13, comprising an amino acid sequence at least 90% identical to a sequence selected from the group consisting of:

- (a) the amino acid sequence of the PCA3 polypeptide comprising the complete amino acid sequence in SEQ ID NO.3, and
- (b) the amino acid sequence of an epitope-bearing portion of any one of the polypeptides of (a) or (b).

15. An antibody having specific binding affinity to the polypeptide or epitope-bearing portion thereof according to claim 14.

16. A method of detecting PCA3 in a sample, comprising:

- a) contacting said sample with an antibody according to claim 15, under conditions such that immunocomplexes form, and
- b) detecting the presence of said antibody bound to said polypeptide.

17 A diagnostic kit comprising:

a) a first container means containing the antibody according to claim 15; and

b) second container means containing a conjugate comprising a binding partner of said monoclonal antibody and a label

18. A hybridoma which produces the monoclonal antibody according to claim 15.

19. A method of treatment of prostate cancer in a mammal, comprising a modulation of a level of differentially expressed PCA3 mRNA such that the level of a first differentially expressed PCA3 mRNA, wherein said first PCA3 mRNA comprises an additional sequence between exon 3 and exon 4a, is superior to that of a second differentially expressed PCA3 mRNA, wherein said second PCA3 mRNA lacks said additional sequence.

20. A method of diagnosing the presence or predisposition to develop prostate cancer in a patient, said method comprising:

a) taking a sample from said patient;

b) determining the amount of differentially expressed PCA3 or RNA or PCA3 protein in said sample, and

c) diagnosing the presence or predisposition to develop prostate cancer in a patient wherein a presence of a long PCA3 mRNA or protein is indicative of a non-malignant state of the prostate, and a presence of a short PCA3 mRNA or protein is indicative of prostate cancer or predisposition to develop prostate cancer.

21 A method of staging prostate cancer in a patient, said method comprising:

- a) taking a sample from said patient,
- b) determining the amount of differentially expressed PCA3 RNA or PCA3 protein in said sample, and
- c) staging prostate cancer in said patient wherein an increase in a level of a short PCA3 mRNA or protein is correlated with an increase in the malignancy of prostate cancer.

22 A method to assess the prostate status of a patient comprising a quantitative determination of a short PCA3 mRNA, associated with a malignant state of prostate and a long PCA3 mRNA, associated with a non-malignant state of prostate, wherein a level of said short PCA3 mRNA with respect to said long PCA3 mRNA can be correlated to the prostate status of said patient

23 The method of claim 22, wherein said quantification of said short and long PCA3 mRNA is carried out simultaneously.

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